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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 00-6328 CR-FERGUSON
21 U.S.C. § 331(a)
21 U.S.C. § 333(a)(2)

MAGISTRATE JUDGE
SNOW

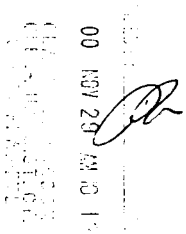
UNITED STATES OF AMERICA,

Plaintiff,

v.

SMLX TECHNOLOGIES, INC.

Defendants.
_____/



INFORMATION

The United States Attorney charges that:

COUNT 1

At all times relevant to this Information, unless otherwise stated:

1. Analyte Diagnostics, Inc., was a Florida corporation, which later became a wholly owned subsidiary of Simplex Medical Systems, Inc., also a Florida corporation, which later purchased a publically traded Colorado corporation, which conducted business under the name Simplex Medical Systems, Inc., which later became known as SMLX Technologies, Inc., a Colorado corporation, all hereinafter referred to as SMLX. SMLX's principal place of business was located in Broward County, Florida.

2. SMLX was engaged in the business of developing, manufacturing and marketing medical devices, to include a saliva based diagnostic test kit for detecting the presence of HIV antibodies in

human saliva, which was marketed under the name "Simplex Rapid HIV Saliva Test."

3. The United States Food and Drug Administration ("FDA") was the agency of the United States government responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in the diagnosis or treatment of disease or other conditions in humans are safe and effective for their intended medical uses and that the labeling of such devices bore true and accurate information. The FDA carried out this responsibility by regulating and monitoring the manufacturing, processing, packaging, labeling and shipment of medical devices.

4. Under the Federal Food, Drug and Cosmetic Act (the Food and Drug Act), 21 U.S.C. § 321(h), a medical "device" was defined, in relevant part, as "an instrument, apparatus, implement, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or animals, . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

5. Pursuant to 21 U.S.C. § 360c(f)(1) and 360e the saliva based HIV test kits relevant to this information are Class III medical devices.

6. Manufacturers of medical devices were required under the Food and Drug Act to obtain FDA "approval"or "clearance" prior to distributing the devices in interstate commerce. The Food and Drug Act defined "interstate commerce," in pertinent part, as meaning "commerce between any State or Territory and any place outside thereof . . ." 21 U.S.C. § 321(b).

7. The medical devices relevant to this information could only be lawfully introduced into interstate commerce if they were (1) approved by the FDA in the form of an approved application

for premarket approval ("PMA") pursuant to 21 U.S.C. § 360(e); (2) found to be substantially equivalent to a device on the market prior to May 28, 1976, or to a subsequently approved Class I or II device, pursuant to 21 U.S.C. § 360(k); or (3) exempted from such approval requirements by an approved application for an investigational device exemption ("IDE"), pursuant to 21 U.S.C. § 360j(g).

8. The medical devices relevant to this information could be lawfully exported from the United States without the above described FDA "approvals" or "clearances" under one of two alternative conditions. First, a person may export an unapproved Class III device pursuant to 21 U.S.C. § 381(e)(2) if the device meets the criteria of 21 U.S.C. § 381(e)(1) and the FDA has determined that the device is not contrary to the public health and safety, and has the approval of the country to which it is intended for export. Second, a person may export an unapproved Class III device under 21 U.S.C. § 382 to any country if the device complies with the laws of that country and has a valid marketing authorization in certain industrialized "listed" countries.

9. In addition to the requirements described in paragraphs 7 and 8 of this information, all medical devices, whether for domestic shipment or export, were required to be manufactured in compliance with "current good manufacturing practices." 21 U.S.C. §§ 360(j) and 382(f)(1). Current good manufacturing practices (cGMP) prescribe the requirements for manufacturing, testing, storing, packaging and distributing a medical device so that the device will be safe and effective. These requirements are set forth in regulations issued by the FDA.

10. The Food and Drug Act made it unlawful to introduce or to deliver for introduction into interstate commerce any medical device that is "adulterated." 21 U.S.C. § 331(a). Pursuant to 21 U.S.C. § 351(h), and the regulations promulgated under 21 U.S.C. § 360j, a medical device is

deemed to be "adulterated" if it was not manufactured, tested, stored, packaged or distributed in accordance with cGMPs. Pursuant to 21 U.S.C. § 351(f), a medical device is deemed "adulterated" if it is a Class III device and it had not yet received FDA "clearance" or "approval" to be shipped or marketed in interstate commerce.

11. At all times relevant to this information, SMLX had not yet obtained FDA "clearance" or "approval" to market the Simplex Rapid HIV Saliva Test kits in the United States, and SMLX had not yet met the requirements to lawfully export Simplex Rapid HIV Saliva Test kits to foreign countries.

12. At all times relevant to this information, SMLX failed to comply with cGMPs with respect to the manufacturing, testing, storing, packaging and distributing of Simplex Rapid HIV Saliva Test kits.

13. From at least December 1995, through on or about July 21, 1998, at Broward County, in the Southern District of Florida, and elsewhere, the defendant,

SMLX TECHNOLOGIES, INC.,

did knowingly and willfully, with the intent to defraud the Food and Drug Administration, purchasers and consumers, introduce into interstate commerce and deliver for introduction into interstate commerce devices, that is, Simplex Rapid HIV Test kits, which where adulterated within the meaning of Title 21, United States Code, Section 351(h), in that the devices had not been manufactured, tested, stored, packaged and distributed in accordance with current good manufacturing practices as required, and which were adulterated within the meaning of Title 21, United States Code, Section 351(f)(1), in that they were Class III devices which were commercially distributed without the required FDA "approvals" and "clearances," and which had not met the

exemption requirements for export under Title 21 United States Code, Sections 381 and 382, in violation of Title 21, United States Code, Section 331(a) and 333(a)(2).

GUY A. LEWIS
UNITED STATES ATTORNEY

ROBERT N. NICHOLSON
ASSISTANT UNITED STATES ATTORNEY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA

v.

SMI X TECHNOLOGIES, INC.

Court Division: (Select One)

___ Miami ___ Key West
X FTL ___ WPB ___ FTP

CASE NO. _____

CERTIFICATE OF TRIAL ATTORNEY*

Superseding Case Information:

New Defendant(s) Yes ___ No ___
Number of New Defendants ___
Total number of counts ___

I do hereby certify that:

1. I have carefully considered the allegations of the indictment, the number of defendants, the number of probable witnesses and the legal complexities of the Indictment/Information attached hereto.

2. I am aware that the information supplied on this statement will be relied upon by the Judges of this Court in setting their calendars and scheduling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C. Section 3161.

3. Interpreter: (Yes or No) NO
List language and/or dialect _____

4. This case will take 1 days for the parties to try.

5. Please check appropriate category and type of offense listed below:

(Check only one)			(Check only one)	
I	0 to 5 days	X	Petty	
II	6 to 10 days		Minor	
III	11 to 20 days		Misdem.	
IV	21 to 60 days		Felony	X
V	61 days and over			

6. Has this case been previously filed in this District Court? (Yes or No) No
If yes:
Judge: _____ Case No. _____
(Attach copy of dispositive order)

Has a complaint been filed in this matter? (Yes or No) No
If yes:
Magistrate Case No. _____
Related Miscellaneous numbers: 99-4797-Snow
Defendant(s) in federal custody as of _____
Defendant(s) in state custody as of _____
Rule 20 from the _____ District of _____

Is this a potential death penalty case? (Yes or No) No

7. Does this case originate from a matter pending in the U. S. Attorney's Office prior to April 1, 1999? ___ Yes X No If yes, was it pending in the Central Region? ___ Yes ___ No

8. Did this case originate in the Narcotics Section, Miami? ___ Yes X No

ROBERT N. NICHOLSON
ASSISTANT UNITED STATES ATTORNEY
Florida Bar No. 933996

*Penalty Sheet(s) attached

REV.6/27/00

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
PENALTY SHEET

Defendant's Name: SMLX Technologies, Inc. No.: _____

Count # I:
Introducing Adulterated Medical Devices Into Interstate Commerce, in violation of Title 21, United States Code, Section 331(a)

*Max Penalty: 5 years' probation and a fine of the greater of $500,000 or twice the amount of the fraud.

Count # :

*Max Penalty:

Count # :

*Max Penalty:

Count # :

*Max Penalty:

Count #:

*Max Penalty:

Count #:

*Max Penalty:

Refers only to possible term of incarceration, does not include possible fines, restitution, special assessments, parole terms or forfeitures that may be applicable.

REV 12/12/96